MAR - 6 2001

July 10, 2000

## SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for the Shaver Ablator 510(k) Number K002088

### A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

### B. Company Contact

Laura D. Seneff, RAC
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

### C. Device Name

| | | |
|---|---|---|
| Trade Name | : | Shaver Ablator |
| Common Name | : | Electrode |
| Classification Names | : | Electrosurgical cutting and coagulation device and accessories, 878.4400 |
| Proposed Class/Device Product Code | : | Class II, GEI, Electrode Electrosurgical |

### D. Predicate/Legally Marketed Devices

UltrAblator™ Electrode
Linvatec Corporation

Dyonics ElectroBlade
Smith & Nephew, Inc.

## E. Device Description

The Shaver Ablator is a combination of a Linvatec arthroscopic shaver blade and a Linvatec UltrAblator™ monopolar electrode. The product configuration combines the mechanical resection of a shaver blade and the ablation and hemostasis functions of an electrode. The Shaver Ablator is packaged in a kit with a generator adapter which is used to attach the electrode portion of the device to the generator. The Shaver Ablator is supplied sterile, single use. The adapter is supplied non-sterile.

## F. Intended Use

The Shaver Ablator is intended to be used in arthroscopic procedures for resection and ablation of soft tissue and hemostasis of blood vessels.

## G. Summary of Technological Characteristics:

The Shaver Ablator combines the existing technologies of the UltrAblator™ Electrode and a Linvatec arthroscopic shaver blade, similar to the Dyonics ElectroBlade. The technologies, design, materials and intended uses are similar for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2001

Ms. Laura D. Seneff, RAC
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K002088
Trade Name: Shaver Ablator
Regulatory Class: II
Product Code: HRX
Dated: December 5, 2000
Received: December 6, 2000

Dear Ms. Seneff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

July 10, 2000



510(k) Number (if known): K002088

Device Name: Shaver Ablator

Indications for Use:

The Shaver Ablator is intended to be used in arthroscopic procedures for resection and ablation of soft tissue and hemostasis of blood vessels.

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002088

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)